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Debate on: Bracing in Adolescent Scoliosis Trial (BrAIST) - will the expenditure pay?

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Adolescent idiopathic scoliosis has been regarded as a disease of relatively benign character without disastrous effects on the individual's health [1].

Therefore, treatment indications can be primarily regarded as aiming to achieve psychological and cosmetic benefits for the patient [2]. In fact, level II evidence has been established for conservative treatment [3], while there is no evidence of higher level for operative treatment [4], and the real existing risks of surgery have not yet been clearly defined [5-7].

A five-year, > $5 million project is being funded by the United States National Institutes of Health, the Canadian Institute of Health Research, and other international spine centers. Although a randomization protocol can only be scientifically used in standardized and therefore comparable treatments and conditions, this study design has been chosen to follow-up patients with scoliosis. Neither the condition, with a variety of different curve patterns, curve stiffness, and different stages of maturity (even when the data show agreement), nor the braces of different standards and different approaches, can be standardized satisfactorily. Therefore, the RCT is not at all the appropriate protocol for attempting to answer the proposed question. Of course, RCTs offer the highest evidence, but only if the design can be estimated as being appropriate, and for this population it is not.

There is already evidence on a high level for bracing, and to expose the control population of this study to the high risks of surgery, in case the scoliosis progresses to an extent with which the patient cannot comply, seems rather negligent. Even more, when one considers (1) the high risks of surgery [5-7], (2) that there will be no guarantee for improvement of the clinical condition [8], and (3) that health related problems can neither be solved nor prevented by surgical treatment [5,9], this study from the patient's perspective seems a risky endeavor.

How reliable can a scientific society be regarded, whose members do not believe in a prospective controlled study on bracing they have established themselves [10] and at the same time can go ahead with surgical treatment, which scientifically raises more questions than it can provide answers?

Last but not least, a measure for brace quality was not initially included in the study protocol! So with whatever strict or not strict inclusion criteria, if the subject (brace) investigated in a RCT cannot be clearly defined, the outcome of that study will say one thing: nothing at all!

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